

**Notice of Allowability**

Application No.

09/759,360

Examiner

Jason M. Nolan, Ph.D.

Applicant(s)

HALFBRODT ET AL.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/12/2005.
2. ☒ The allowed claim(s) is/are 15-24,26,29,30,34 and 45-48.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### DETAILED ACTION

**Claims 15-24, 26, 29-30, 34, and 45-48** are currently pending in the instant application. **Claims 15-22 and 29-30** have been amended and **Claims 45-48** are new.

#### *Priority*

Acknowledgement is made of Applicant's claim for priority via US Provisional Patent Application 60/178,324, filed on January 27, 2000.

#### *Response to Arguments/Amendments*

Applicant's arguments and amendments to the claims, see Amendment – After Non-Final Rejection, filed 12/12/2005, with respect to the 112, 1<sup>st</sup> paragraph, 102(b), and 103(a) as well as all objections, have been fully considered and are persuasive. The rejections of **Claims 15-24, 26, 29, 30, 32-38, 40, and 42-44** are withdrawn.

#### *Examiner's Amendment*

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

1. In **Claim 45, line 3**, after "phenyl-1H-" and before "-6-yl]oxy]" delete "benzimidazol" and insert - - benzimidazol - -.
2. In **Claim 45, line 4**, after "phenyl-1H-" and before "-6-yl]oxy]" delete "benzimidazol" and insert - - benzimidazol - -.

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3. In **Claim 48, line 2**, after "phenyl-1H-" and before "-6-yl]oxy]" delete "benzimidazol" and insert - - benzimidazol - -.

### ***Reasons for Allowance***

The present invention pertains to a method for treating chronic inflammation comprising the administration of a benzimidazole compound of formula II in Claim 15 to a patient in need thereof. The treatment of inflammation, in this case, is via the inhibition of microglial activation, which was known in the art (since at least 2000) to stop the release of proinflammatory and cytotoxic factors, which can be accomplished using non-steroidal anti-inflammatory drugs (Halliday *et al.* Clinical and Experimental Pharmacology and Physiology, January 2000, Vol. 27 (1-2), p. 1-8). Additionally, the treatment of inflammation with benzimidazole compounds has been known since at least 1967 (Rohrbach *et al.* FR 1561049). The Applicants have shown in Example 307: Inhibition of Microglia Activation (Specification, page 199a), that the compounds of formula II inhibit microglia activation through *in vitro* and *in vivo* studies. Therefore, Applicants have met their burden of disclosing that the methods of treating inflammation with the compounds according to formula II in Claim 15 via the inhibition of microglia activation is a novel and enabled invention and no prior art anticipates or renders this invention obvious.

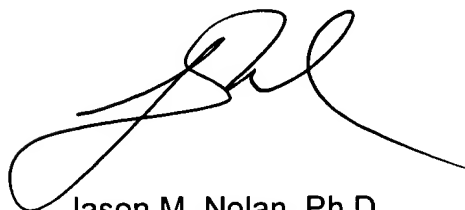
The closest prior art are the compounds disclosed by Kuhnke *et al.* (WO 9507263/DE 4330959; see office action dated 3/23/2004), which were leads for the treatment of blood disorders and the compound (RN 160062-17-9) disclosed by Guthrie *et al.* (US Patent 5344843) which was a lead for the inhibition of carnitine

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acyltransferase 1 (CAT-1) in the prevention of ischemic tissue and treatment of cardiac infarction.

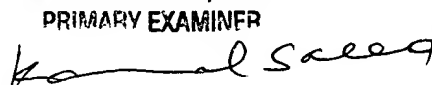
### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is **Jason.Nolan@uspto.gov**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph McKane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for +published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Date: May 23, 2006